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Testing efficacy of individual components of substance use prevention interventions

Submission date
31/01/2016

Recruitment status
No longer recruiting

Registration date
12/04/2016

Overall study status
Completed

Last Edited
08/04/2016

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Abuse of alcohol and illegal drugs in young people has increased dramatically. There is a wide range of research looking at the effectiveness of different programs to prevent alcohol and drug abuse, but little is known about how they really work. Prevention generally use a combination of techniques to try to help participants from drug and alcohol abuse, however it is not really known which aspects of the programs are responsible for the resulting positive changes (i.e. resisting drugs and alcohol). Knowing exactly what it is in the programs that are able to help prevent drug and alcohol abuse could help to streamline these programs so that they are more effective and efficient. The aim of this study is to compare four single components from school-based alcohol and/or drug prevention programs in school-age children across four different countries, in order to find out which is the most effective strategy.

Who can participate?
Children aged between 13 and 14 who attend participating public/government run schools.

What does the study involve?
In each participating country, six schools are randomly allocated to one of two groups. In each country, three of the schools continue with their usual curriculum throughout and three schools take part in the program, which is slightly different in each country. In Italy, the program consists of two two-hour classroom-based sessions and involves learning how to say no to alcohol and marijuana. In the Netherlands, the program is delivered to both students and parents. For the students, this involves a one hour digital module related to alcohol abuse and parents' alcohol related rules. For the parents, this involves a parents' meeting delivered by health and social /care professionals including a brief presentation, a shared discussion and a flyer to take home. In Israel, the program consists of two two-hour interactive classroom-based sessions about reducing positive attitudes towards alcohol and drugs. In Canada, the program consists of two two-and a-half hour personality-targeted sessions including group-based discussions and exercises about how to cope with vulnerability linked to certain parts of the personality (such as anxiety, sensation seeking, hopelessness, impulsiveness). Participants in all counties complete a number of questionnaires at the start of the study and one month after the program is complete in order to assess their ability to resist pressure to use alcohol and drugs, self-control and how well they are coping.

What are the possible benefits and risks of participating?
Participants who take part in the program may be able to better resist alcohol and drugs. There are no risks involved with taking part in this study.

Where is the study run from?
The study takes place in 24 schools in Italy, the Netherlands, Israel and Canada.

When is the study starting and how long is it expected to run for?
September 2015 to March 2016

Who is funding the study?
European Union's Seventh Framework Programme (Belgium)

Who is the main contact?
Professor Fabrizio Faggiano
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
A randomised controlled study to test the effect of individual intervention components on effective mediators for school-based prevention of alcohol abuse and illicit drug use in adolescence

Study objectives
The aim of the study is to evaluate the effects of 4 single school-based intervention components on the mediators causally related to prevention of adolescent alcohol abuse and illicit drug use in students aged 13-14.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethical Committee Of Azienda Ospedaliera Universitaria "Maggiore Della Carità", 02/10/2015 ref: 216/15

Study design
Four two-arm parallel-group randomised controlled trials

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
School

Study type(s)
Prevention

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet.

Health condition(s) or problem(s) studied
Alcohol and substance abuse

Interventions
In each participating country, schools are randomised to one of the two groups (6 schools per participating country with two classes each school – 3 schools in the intervention group and 3 in the control group).

Italy
Intervention group: Participants in the intervention group receive two units from Unplugged (original version) about promotion of refusal skills related to alcohol and marijuana. This involves two two-hour interactive classroom-based sessions delivered by previously trained teachers including teacher-led discussions, workbook individual activities and role-plays.
Control group: Participants continue with their usual curriculum. Control group schools will solely participate in the measurement of the study outcomes.

The Netherlands
Intervention group: Participants in the intervention group receive two units from PAS (Prevention of Alcohol use in Adolescence - original version) about promotion of self-control

related to alcohol abuse and parents' alcohol related rules. This involves one digital module delivered by previously trained teachers including short films, animations and classroom-based interactive tasks + one parents' meeting delivered by health and social/care professionals including a brief presentation, a shared discussion and a flyer to take home. The module lasts for two hours, with one hour for the students' intervention and one hour for the parents' intervention.
Control group: Participants continue with their usual curriculum. Control group schools will solely participate in the measurement of the study outcomes.

Israel
Intervention group: Participants in the intervention group receive two units from Unplugged (adapted English version) about reduction of positive attitudes towards alcohol and drugs. This involves two two-hour interactive classroom-based sessions delivered by previously trained teachers including games, teacher-led discussions and group activities.
Control group: Participants continue with their usual curriculum. Control group schools will solely participate in the measurement of the study outcomes.

Canada
Intervention group: Participants in the intervention group receive two units from Preventure (original version) about promotion of adaptive coping strategies with vulnerability associated to specific personality traits (such as anxiety, sensation seeking, hopelessness, impulsiveness). This involves two two and a half hour personality-targeted sessions delivered by a trained facilitator including group-based discussions and exercises.
Control group: Participants continue with their usual curriculum. Control group schools will solely participate in the measurement of the study outcomes.

In all countries, participants in both groups are followed up one month after completion of the intervention.

Intervention Type
Behavioural

Primary outcome measure
Italy:
Ability to resist pressure and offers to use alcohol and illicit substances assessed using two items taken from the EU-Dap Questionnaire at baseline and one month after the intervention.

Netherlands:
1. Self-control assessed at using 13 items taken from the PAS questionnaire at baseline and one month after the intervention
2. Parental rules about alcohol use be assessed at baseline and one month after the intervention by 10 items taken from the PAS questionnaire at baseline and one month after the intervention

Israel:
Attitudes towards substance use assessed at baseline and one month after the end of the intervention by 11 items taken from the EU-Dap questionnaire at baseline and one month after the intervention.

Canada:
Coping assessed using the Brief COPE Inventory used for the evaluation of Preventure Programme at baseline and one month after the intervention.

Secondary outcome measures
Italy:
1. Self-control assessed using 13 items taken from the PAS questionnaire at baseline and one month after the end of the intervention
2. Parental rules about alcohol use assessed using 10 items taken from the PAS questionnaire at baseline and one month after the end of the intervention
3. Attitudes towards substance use assessed using 11 items taken from the EU-Dap questionnaire at baseline and one month after the end of the intervention
4. Coping assessed using the Brief COPE Inventory used for the evaluation of Preventure Programme at baseline and one month after the end of the intervention

Netherlands:
1. Ability to resist pressure and offers to use alcohol and illicit substances assessed using two items taken from the EU-Dap Questionnaire at baseline and one month after the intervention
2. Attitudes towards substance use assessed using 11 items taken from the EU-Dap questionnaire at baseline and one month after the end of the intervention
3. Coping assessed using the Brief COPE Inventory used for the evaluation of Preventure Programme at baseline and one month after the end of the intervention

Israel:
1. Ability to resist pressure and offers to use alcohol and illicit substances assessed using two items taken from the EU-Dap Questionnaire at baseline and one month after the intervention
2. Self-control assessed at using 13 items taken from the PAS questionnaire at baseline and one month after the intervention
3. Parental rules about alcohol use assessed using 10 items taken from the PAS questionnaire at baseline and one month after the end of the intervention
4. Coping assessed using the Brief COPE Inventory used for the evaluation of Preventure Programme at baseline and one month after the end of the intervention

Canada:
1. Ability to resist pressure and offers to use alcohol and illicit substances assessed using two items taken from the EU-Dap Questionnaire at baseline and one month after the intervention
2. Attitudes towards substance use assessed using 11 items taken from the EU-Dap questionnaire at baseline and one month after the end of the intervention
3. Self-control assessed at using 13 items taken from the PAS questionnaire at baseline and one month after the intervention
4. Parental rules about alcohol use assessed using 10 items taken from the PAS questionnaire at baseline and one month after the end of the intervention

Overall study start date
01/09/2015

Completion date
31/03/2016

Eligibility

Key inclusion criteria

1. Students attending public/government schools
2. At least two classes attended by students aged 13-14
3. Not participating in other major prevention intervention for alcohol abuse and/or illicit drug use targeted to the classes of interest

Participant type(s)
Healthy volunteer

Age group
Child

Lower age limit
13 Years

Upper age limit
14 Years

Sex
Both

Target number of participants
260 students per trial, evenly distributed across study groups (130 students in the intervention group, 130 students in the control group). It corresponds to 12 classes of 25 students per participating country (6 schools per participating country with two classes each school). The total sample will be composed of 1,040 students aged 13-14.

Key exclusion criteria
1. Students with special needs
2. Thsoe whose parents opt out from the study

Date of first enrolment
01/10/2015

Date of final enrolment
01/03/2016

Locations

Countries of recruitment
Canada

Israel

Italy

Netherlands

Study participating centre

Università del Piemonte Orientale
Department of Traslational Medicine
Via Solaroli 17
Novara
Italy
28100

Study participating centre
University of Amsterdam
Department of Psychology
Weesperplein 4
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Study participating centre
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Sponsor information

Organisation
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Sponsor details
Alice Rap Project
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Sponsor type
Other

Website
www.alicerap.eu

ROR
https://ror.org/02a2kzf50

Funder(s)

Funder type
Research organisation

Funder Name
Seventh Framework Programme

Alternative Name(s)
EC Seventh Framework Programme, European Commission Seventh Framework Programme, EU Seventh Framework Programme, European Union Seventh Framework Programme, FP7

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location

Results and Publications

Publication and dissemination plan
The study protocol and the results will be published in open access journals. Multi-centric results will be published in a summary paper before the publication of local results.

Intention to publish date
31/03/2016

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Available on request